UNITED STATES DISTRICT COURT WESTERN DISTRICT OF LOUISIANA SHREVEPORT DIVISION

ANNIE V. KENNEDY AS TUTRIX AND ON BEHALF OF THE MINOR CHILD L.K., MINOR CHILD OF THE DECEDENT CIVIL ACTION NO. 13-3132

VERSUS

JUDGE S. MAURICE HICKS, JR.

PFIZER, INC., ASTRAZENECA PHARMACEUTICALS, LP, UCB PHARMACEUTICALS, INC., AND XYZ MANUFACTURER MAGISTRATE JUDGE HORNSBY

MEMORANDUM RULING

Before the Court is Defendant AstraZeneca Pharmaceuticals, LP's ("AstraZeneca") Rule 12(b)(6) Motion to Dismiss (Record Document 27). AstraZeneca seeks dismissal of Plaintiff Annie V. Kennedy's ("Plaintiff Kennedy") product liability claims under the Louisiana Products Liability Act, La. Rev. Stat. §§ 9:2800.51-60 ("LPLA"). See id. AstraZeneca based its Rule 12(b)(6) motion on two grounds: (1) that Plaintiff Kennedy's LPLA claims are prescribed; and (2) that Plaintiff Kennedy failed to meet the minimum pleading standards under Rule 8(a)(2). See id. For the reasons which follow, AstraZeneca's motion is GRANTED, and Plaintiff Kennedy's claims against AstraZeneca are DISMISSED WITH PREJUDICE.1

FACTUAL BACKGROUND

Plaintiff Kennedy is the biological, maternal aunt and the court-appointed Dative Tutrix of the minor child L.K. ("L.K."). See Record Document 1 at ¶ 2. The First Judicial

¹Because the Court has granted AstraZeneca's Rule 12(b)(6) Motion to Dismiss based on Plaintiff Kennedy's failure to meet the minimum pleading standards under Rule 8(a)(2), it need not reach AstraZeneca's prescription argument.

Court of Caddo Parish, Louisiana appointed Plaintiff Kennedy as Dative Tutrix of L.K. on June 18, 2012. See id. L.K. is the minor son (age not alleged) of the late Lashunda Renee Kennedy ("Kennedy" or "L.K.'s mother"), who died on October 6, 2011. See id. at ¶ 3. Defendant Pfizer, Inc. ("Pfizer") is the manufacturer of the medications Dilantin and Geodon. See id. at ¶ 4. Defendant AstraZeneca is the manufacturer of the medication Seroquel. See id. UCB Pharmaceuticals, Inc. ("UCB") is the manufacturer of the medication Keppra. See id. XYZ Manufacturer ("XYZ") is a manufacturer of Valproic Acid. See id. All four of these medications are anti-seizure medications. See id. at ¶¶ 8, 11.

On July 10, 2011, Kennedy was taken by ambulance to Louisiana State University Health Science Center in Shreveport ("LSUHSC-S") due to "altered mental status and non-verbal, uncooperative and aggressive behavior." Id. at ¶ 7. Kennedy began to suffer "seizure like activity and rapid renal deterioration." Id. at ¶ 8. Kennedy first ingested the prescribed medication Keppra on July 10, 2011. See id. Kennedy first took the prescribed medication Dilantin on July 12, 2011. See id. at ¶ 9. These two medications did not stop the seizures, so Kennedy's dosage of both medications was increased on July 14, 2011. See id. at ¶ 10. By July 29, Kennedy was receiving both of these medications intravenously. See id. at ¶ 11. Doctors also prescribed Valproic Acid for her on July 29. See id.

On July 31, 2011, Kennedy complained of itching, and doctors prescribed Benadryl to stop the itching. See id. at ¶ 12. From July 31, 2011 to August 22, 2011,

²AstraZeneca explains in its Motion to Dismiss that Seroquel is not an anti-seizure medication, but the Court will take all factual allegations in the complaint as true for the purposes of the Rule 12(b)(6) Motion to Dismiss. <u>See</u> Record Document 27-1 at 2, n. 1.

Kennedy's seizures continued intermittently, her itching worsened, and she developed rashes, blisters, and ulcers. See id. at ¶¶ 12-16. Throughout this period, Kennedy continued to receive Dilantin, Keppra, and Valproic Acid, but doctors discontinued these medications on August 22, 2011, along with the medication Seroquel.³ See id. at ¶ 16. On August 22, 2011, Kennedy's medical records indicate that doctors were concerned that Kennedy had Stevens - Johnson Syndrome ("SJS"). See id. Doctors speculated that the rashes were "thought to be secondary to medication reaction." Id. at ¶ 17.

After August 22, 2011, Kennedy's condition "severely decline[d]." <u>Id.</u> Her rashes and ulcers were described as "sloughed lesions" in her medical records; her seizures continued, but by this point she had been taken off all anti-seizure medications. <u>Id.</u> at ¶ 19. Kennedy's condition continued to deteriorate until her death on October 6, 2011. <u>See id.</u> at ¶ 20.

On July 9, 2012, Plaintiff Kennedy filed suit ("the first suit") on behalf of L.K. against Pfizer in this Court, alleging that the Dilantin Kennedy ingested was defective and caused her death from SJS. See Kennedy v. Pfizer, Inc., No. 12-1858, 2013 WL 4590331 (W.D.La. August 28, 2013). Plaintiff Kennedy's causes of action in the first suit, as in the instant action, included all four of the causes of action under the LPLA. See id. On August 28, 2013, this Court granted Pfizer's Rule 12(b)(6) Motion to Dismiss all of Plaintiff Kennedy's claims. See id. at *6. Plaintiff Kennedy did not file a notice of

³Confusingly, before this portion of the complaint, the complaint never asserted that Seroquel had been administered to Kennedy, nor did it include a date on which the administration of this medication began. The complaint only mentions Seroquel three other times, and then only for the purpose of identifying AstraZeneca as its manufacturer or quoting a doctor's speculation from medical records. See Record Document 1 at ¶¶ 4, 16, 19, 22.

appeal; she did not seek leave to amend the original complaint. See Record Document 28 at ¶ 9.

The instant action, alleging that Defendants Pfizer, AstraZeneca, UCB, and XYZ are liable to Plaintiff Kennedy for the wrongful death of L.K.'s mother under all four of the causes of action under the LPLA, commenced on November 25, 2013. See Record Document 1. Now before the Court is AstraZeneca's Rule 12(b)(6) Motion to Dismiss.

See Record Document 27. Plaintiff Kennedy filed a memorandum in opposition to AstraZeneca's motion, and AstraZeneca filed a reply. See Record Documents 39 & 40.

LAW AND ANALYSIS

I. LEGAL STANDARDS

Rule 8(a)(2) of the Federal Rules of Civil Procedure governs the requirements for pleadings that state a claim for relief. Such a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." F.R.C.P. 8(a)(2). The standard for the adequacy of complaints under Rule 8(a)(2) was once the more plaintiff-friendly "no set of facts" standard from Conley v. Gibson, 355 U.S. 41, 47, 78 S.Ct. 99, 102 (1957). However, the Supreme Court changed to a "plausibility" pleading standard in Bell Atl. v. Twombly, 550 U.S. 544, 557, 127 S. Ct. 1955, 1966 (2007), and its progeny. Under this standard, "factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Id. at 555, 127 S.Ct. at 1965. If a pleading only contains "labels and conclusions" and "a formulaic recitation of the elements of a

cause of action," the pleading does not meet the standards of Rule 8(a)(2). Ashcroft v. Igbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 1949 (2009) (internal citation omitted).

In deciding a Rule 12(b)(6) motion to dismiss, courts "generally confine [their] analysis to the complaint and its proper attachments." Hale v. King, 642 F.3d 492, 499 (5th Cir. 2011). Courts must also accept all allegations in a complaint as true, but courts do not have to accept legal conclusions as facts. See Iqbal, 556 U.S. at 678, 129 S.Ct. at 1949. Only those complaints that are facially plausible under the Iqbal and Twombly standards survive a Rule 12(b)(6) motion to dismiss. A dismissal on a Rule 12(b)(6) motion disposes of a case "at the point of minimum expenditure of time and money by the parties and the court." Twombly, 355 U.S. at 558, 127 S.Ct. at 1966 (internal citations and quotation omitted).

The LPLA provides "the exclusive theories of liability for manufacturers of products and establishes the exclusive theories of liability for manufacturers for damage caused by their products." La. R.S. § 9:2800.52. The LPLA provides that a manufacturer can be held liable for its product if and only if the product is unreasonably dangerous in at least one of four ways: (1) unreasonably dangerous in construction or composition; (2) unreasonably dangerous in design; (3) unreasonably dangerous because an adequate warning about the product has not been provided; (4) unreasonably dangerous because it does not conform to an express warning of the manufacturer about the product. See La. R.S. 9:2800.54.

II. ANALYSIS

Plaintiff Kennedy alleged that AstraZeneca's medication Seroquel was unreasonably dangerous in all four of the ways set forth in the LPLA. <u>See</u> Record Document 1 at ¶¶ 22-24. Applying the <u>Twombly</u> and <u>Iqbal</u> standards for determining whether a complaint is sufficient under Rule 8(a)(2), it is clear that Plaintiff Kennedy's complaint and its allegations are not sufficient to state a claim upon which relief can be granted against AstraZeneca.

A. Construction or Composition

La. R.S. 9:2800.55 is the portion of the LPLA that governs the requirements for a construction or composition defect claim. Section 2800.55 provides that "a product is unreasonably dangerous in construction or composition if, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer."

Plaintiff Kennedy alleged that Seroquel was "unreasonably dangerous in [its] construction and composition." See Record Document 1 at ¶ 22. While the complaint contains a few factual allegations relating to Dilantin, it is silent as to any additional factual allegations regarding Seroquel's alleged construction or composition defects.

See generally Record Document 1. The complaint, therefore, does not state how Seroquel allegedly "deviated in a material way from [AstraZeneca's] specifications or performance standards or from otherwise identical products" made by AstraZeneca. See id.; see also La. R.S. 9:2800.55.

Applying the <u>Iqbal</u> standard, Plaintiff Kennedy's factual allegations supporting her construction and composition defect claim against AstraZeneca clearly fail to meet the requirements of Rule 8(a)(2). <u>See Iqbal</u>, 556 U.S. at 678, 129 S.Ct. at 1949. Other complaints that have only "recit[ed] the allegation that defendant is liable to plaintiff for providing a product that was unreasonably dangerous in construction or composition" have been dismissed on a Rule 12 (b)(6) motion to dismiss. <u>Harris v. Merck & Co.</u> No. 12-1446, 2012 WL 538470, *2 (W.D.La. Nov. 1, 2012). The allegations in Plaintiff Kennedy's complaint regarding the construction and composition of Seroquel are a clear example of mere "labels and conclusions" and "a formulaic recitation of the elements of a cause of action." <u>Iqbal</u>, 556 U.S. at 678, 129 S.Ct. at 1949. Thus, such allegations do not state a claim for relief under Rule 8(a)(2) and/or Rule 12(b)(6).

B. Design

Section 2800.56 of the LPLA governs the requirements for a design defect claim. Section 2800.56 provides:

A product is unreasonably dangerous in design if, at the time the product left its manufacturer's control:

- (1) there existed an alternative design for the product that was capable of preventing the claimant's damage; and
- (2) the likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product. An adequate warning about a product shall be considered in evaluating the likelihood of damage when the manufacturer has used reasonable care to provide the adequate warning to users and handlers of the product.

Plaintiff Kennedy alleged that Seroquel was "unreasonably dangerous in [its] . . . design." See Record Document 1 at ¶ 22. Though Plaintiff Kennedy alleged a few facts about Dilantin, she did not set forth any more factual allegations regarding Seroquel's alleged design defects. See generally Record Document 1. The complaint is silent as to whether there is any alternative design for Seroquel that was capable of preventing Plaintiff Kennedy's damage. See id. The failure to plead that an alternative design was available for the product is enough to doom the complaint, as the existence of an alternative design is a necessary element to a design defect claim under Section 2800.56(1) of the LPLA. See Rios v. City of Del Rio, 444 F.3d 417, 420 (5th Cir. 2006) ("the complaint must contain either direct allegations on every material point necessary to sustain a recovery...or contain allegations from which an inference fairly may be drawn that evidence on these material points will be introduced at trial") (internal citations omitted).

Plaintiff Kennedy likewise failed to adequately plead the second element of a design defect claim. See La. R.S. 9:2800.56(1). The second element of a design defect claim requires the plaintiff to prove that the gravity of the damage that the product would cause "outweighed the burden on the manufacturer of adopting [the alleged] alternative design and the adverse effect, if any, of such alternative design on the utility of the product." Id. Because Plaintiff Kennedy failed to allege that an alternative design existed, it is impossible for the complaint to have sufficiently alleged the second element of a design defect claim, which involves a balancing test between the gravity of the

The Court is aware that in <u>Harris</u>, the plaintiff's design defect claim survived a Rule 12(b)(6) motion to dismiss even though it did not plead the existence of an alternative design. <u>See Harris</u>, 2012 WL 538470, *2. However, this Court finds that <u>Harris</u> is factually distinguishable and materially different from the complaint in the instant matter.

damage the product would cause as currently designed and the burden and effects of adopting the alternative design. See id. Therefore, Plaintiff Kennedy's allegations regarding a design defect amount to mere "labels and conclusions" and "a formulaic recitation of the elements of a cause of action." Iqbal, 556 U.S. at 678, 129 S.Ct. at 1949. Such allegations simply do not state a claim for relief under Rule 8(a)(2) and/or Rule 12(b)(6).

C. Inadequate Warning

Section 2800.57 of the of the LPLA governs the requirements for an inadequate warning claim. Section 2800.57 provides:

a product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

Louisiana courts also apply the "learned intermediary doctrine" to inadequate warning claims involving prescription drugs. See Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 265 (5th Cir. 2002). Under this doctrine, the manufacturer of the drug at issue "discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm from a drug." Id. This doctrine involves a two-pronged test. See id. "First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician." Id. at 265-66. "Second, the plaintiff must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury." Id. at 266.

Plaintiff Kennedy alleged that Seroquel did not adequately warn of its "likely hood (*sic*) to cause consumers to develop Steven Johnson Syndrome (*sic*)." See Record Document 1 at ¶ 23. This allegation, while more specific than the bare allegations relating to Plaintiff Kennedy's construction or composition and design claims, fails under Rule 8(a)(2) and Rule 12(b)(6).

Two recent cases are instructive as to the pleading requirements for an inadequate warning claim. The first such case is <u>Harris</u>, wherein the court found that an allegation that a warning that failed to indicate the potential negative side effects of taking an 80-milligram dosage was "barely sufficient" under Rule 8(a)(2). <u>See Harris</u>, 2012 WL 538470, *4. There, the plaintiff had alleged that "[i]f Merck had [rendered an adequate warning concerning Zocor], prescribers such as Plaintiff's prescriber would not have prescribed Zocor in patients, such as the Plaintiff, and would have switched from Zocor to safer products, or would have refrained wholly from any use of Zocor." <u>Id.</u> at *4. The second instructive case is <u>Watson v. Bayer Healthcare Pharms., Inc.</u> No. 13-212, 2013 WL 1558328 (E.D.La. April 11, 2013). In contrast to <u>Harris</u>, the <u>Watson</u> court dismissed the plaintiff's claims because the plaintiff had "failed to allege facts showing a causal connection between her injury" and the product's warning. <u>Id.</u> at *5.

The complaint in the instant action is more similar to <u>Watson</u> than <u>Harris</u>. Plaintiff Kennedy's complaint in the instant action makes no allegations like those in <u>Harris</u>. Instead, the complaint merely states that the warning was defective because it failed to warn of the potential for the development of SJS. <u>See</u> Record Document 1 at ¶ 23. Therefore, Plaintiff Kennedy's allegations regarding an inadequate warning claim under the LPLA fail to state a claim for relief under Rule 8(a)(2) and/or Rule 12(b)(6).

D. Express Warranty

Section 2800.58 of the LPLA governs the requirements for a nonconformity to express warranty claim. Section 2800.58 provides that a product qualifies as unreasonably dangerous "when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue."

Plaintiff Kennedy alleged that Seroquel was "unreasonably dangerous in that [it] did not conform to [AstraZeneca's] express warranties-specifically that the benefit of [its] use outweighed any potential harm presented to the consuming public." Record Document 1 at ¶ 24. In <u>Aucoin v. Amneal Pharms., LLC</u>, No. 11-1275, 2012 WL 2990697 (E.D.La. July 20, 2012), the court granted a Rule 12(b)(6) motion to dismiss the express warranty claims because the plaintiff failed to allege that the defendant had advertised its product; that the defendant had detailed its product to doctors; that the defendant had made any other form of communication regarding the product; or that the plaintiff was induced to take the product because of any alleged express warranty. <u>See id.</u> The complaint in that case contained more factual allegations relating to the product and the injury than the complaint in the instant matter. Nevertheless, the court in <u>Aucoin</u> dismissed the plaintiff's express warranty claims. <u>See id.</u>

Here, Plaintiff Kennedy failed to make any of the factual allegations deemed necessary in <u>Aucoin</u>. Of particular significance is Plaintiff Kennedy's failure to allege that Seroquel's express warranty induced the use of the product, as the only way a

plaintiff can recover for breach of express warranty is "if the express warranty has

induced the claimant or another person or entity to use the product." La. R.S. 9:2800.58;

See also Rios, 444 F.3d at 420. Therefore, because Plaintiff Kennedy failed to allege

any of the factual allegations found necessary in Aucoin, particularly the allegation that

the express warranty induced the use of the product, she has failed to state a claim for

relief for an express warranty defect under Rule 8(a)(2) and/or Rule 12(b)(6).

CONCLUSION

The bare allegations in Plaintiff Kennedy's complaint do not "raise a right to relief

above the speculative level," and therefore do not meet the minimum pleading

standards of Rule 8(a)(2). Twombly, 550 U.S. at 555, 127 S. Ct. at 1965. Because

Plaintiff Kennedy has failed to meet these minimum pleading standards, she has not

stated a claim upon which relief can be granted for any of her LPLA claims. Therefore,

Defendant AstraZeneca's Rule 12(b)(6) Motion to Dismiss for failure to state a claim

upon which relief can be granted is hereby **GRANTED**. All of Plaintiff Kennedy's claims

against AstraZeneca are hereby **DISMISSED WITH PREJUDICE**.

An order consistent with the terms of the instant Memorandum Ruling shall issue

herewith.

THUS DONE AND SIGNED, in Shreveport, Louisiana, this 15th day of August,

2014.

S. MAURICE HICKS, JR.

UNITED STATES DISTRICT JUDGE